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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,597	03/14/2005	Yukio Ando	5094-0101PUS1	3475

2292 7590 12/28/2006
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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	12/28/2006	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 12/28/2006.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,597	ANDO ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-16,18-25,28-30 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,14-16,18-25,28-30 and 32-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Group I, Claims 1-35, drawn to a preparation comprising at least a collagen and an oligonucleotide for gene conversion, and a method of converting a specific base on a genome gene in a nucleus of a cell, which comprises contacting a preparation comprising at least a collagen and an oligonucleotide with a cell, and a method of treating a genetic disease comprising contacting a preparation comprising at least a collagen and an oligonucleotide with a cell in a living body by one of several possible routes of administration.

A species restriction is required under 35 U.S.C. 121 and 372. This application contains claims, Claim 6, directed to more than one species of oligonucleotide compositions. This composition cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art (WO 01/097857, December 27,2001, * of record). Kubota et al teaches preparations for delivering oligonucleotides into a cell substantially as claimed in Claims 1 and 2. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species, wherein the oligonucleotide is, specifically:

i) a RNA/DNA chimeric, or

ii) a DNA oligonucleotide.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple oligonucleotide compositions that are structurally distinct. The numerous variations in the number, position and type of nucleotide bases result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect an RNA/DNA chimeric oligonucleotide to have the same chemical and biological properties as a DNA oligonucleotide. Each of the nucleotide moieties confers a unique, non-obvious, distinctly different technical feature onto the nucleic acid composition that will directly impact the bioavailability, metabolism or bioactivity of the

compound. As the technical feature, an oligonucleotide, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

A search for a RNA/DNA chimeric oligonucleotide would not be co-extensive with a search for a DNA chimeric oligonucleotide. Further, a reference rendering a DNA chimeric oligonucleotide as anticipated or obvious over the prior art would not necessarily also render a RNA/DNA chimeric oligonucleotide as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named oligonucleotide composition species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claim 1, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 1.

A species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of particulate form. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species, wherein the particulate form is, specifically:

i) solution-like, as recited in Claim 11, or

ii) solid-like, as recited in Claim 19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple states of matter that are structurally distinct. Each of the particulate states confers a unique, non-obvious, distinctly different technical feature onto the composition that will directly impact the bioavailability, toxicity or bioactivity of the compound. As the technical feature, a composition comprising a collagen and an oligonucleotide, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, the requirement for unity of invention is not fulfilled.

A search for a solid-like particulate form would not be co-extensive with a search for a solution-like particulate form. Further, a reference rendering a solution-like particulate form as anticipated or obvious over the prior art would not necessarily also render a solid-like particulate form as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named particulate form species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 2, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 2.

A species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of cells. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species, wherein the cell is, specifically:

i) a mammalian cell, as recited in Claim 23, or

ii) a yeast or fungal cell, as recited in Claim 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple cells that are structurally distinct. The biologically unrelated cell types are not obvious variations of each other because one skilled in the art does not expect a yeast cell to have the same immunological and biological capacity as a mammalian cell. One of ordinary skill in the art could readily consult any cell biology reference textbook (e.g., *Molecular Biology of the Cell*, Alberts et al., Garland Publishing; *Developmental Biology*, Gilbert, S., Sinauer Associates, Inc) describing the structure, characteristics and biological properties for each of the cells and organisms, and would appreciate that based on such reference disclosures alone or in combination, that these cells and organisms are distinct and separate. As the technical feature, a eukaryotic cell, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

A search for a mammalian cell would not be co-extensive with a search for a yeast cell. Further, a reference rendering a mammalian cell as anticipated or obvious over the prior art would not necessarily also render a fungal cell as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named cell species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claim 22, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 22.

A species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of administration routes. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species, wherein the route of administration is one specific route from the list consisting of the routes recited in Claim 32.

The administration species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple, distinctly different routes of administration. Each of the administration route species is optimized for delivering the composition to a particular target cell in a target tissue or organ, that are not obvious variants of each other, and thus each method step will directly impact the bioavailability or bioactivity of the compound. As the technical feature, a means of administering a composition to a subject linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, the requirement for unity of invention is not fulfilled.

A search for subcutaneous administration would not be co-extensive with a search for oral administration. Further, a reference rendering intramuscular administration as anticipated or obvious over the prior art would not necessarily also render organ surface administration as

anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named administration route species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claim 32, and claims dependent therefrom correspond to all the species listed above.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) and/or species election(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CCFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER